MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS)
CARDIAC CATHETERIZATION SERVICES STANDARD ADVISORY COMMITTEE (CCSAC) MEETING

Thursday, December 17, 2020

Zoom Meeting

APPROVED MINUTES

I. Call to Order

Chairperson Madder called the meeting to order at 7:30 a.m.

A. Members Present and participating remotely:

Ryan Madder, MD, Chairperson – Spectrum Health – Kent County
Kyle Sheiko, Vice-Chairperson – Michigan Outpatient Vascular Institute (MOVI) – Oakland County
Khaldoon Alaswad, MD, FACC, FSCAI – Henry Ford Health System (HFHS) – Wayne County
Omar E. Ali, MD – Detroit Medical Center (DMC) – Wayne County
Edouard Daher, MD – Eastlake Cardiovascular, PC – Oakland County
William R. Felten, MD, MSHAL, FACC – Midland County
Carlos Fernandez, DO – Edward Sparrow Hospital – Ingham County
Anita L. Hart, MD, FACP, SFHM – Blue Cross Blue Shield of Michigan – Oakland County
Srinivas Koneru, MD – K heart & Vascular Institute, PLLC – Macomb County
William S. Porter, RN – UAW Retiree Medical Benefits Trust – Wayne County
Mansoor A. Qureshi, MD – Trinity Health Michigan – Washtenaw County
Fadi A. Saab, MD – Advanced Cardiac & Vascular Centers for Amputation Prevention – Kent County
Frank Saltiel, MD, FACC, FSCAI – Ascension Michigan – Kalamazoo County
Steven B. H. Timmis, MD FACC – HeartPointe Cardiology (Formerly Northpointe Heart Center) – Oakland County (joined late)
Justin Trivax, MD – Beaumont Health – Oakland County
Douglas J. Wunderly, MD – Bronson Healthcare Group/Advanced Cardiac Healthcare, PLC – Kalamazoo County (joined late)

B. Members Absent:

Susanne Mitchell – International Union, UAW

C. Michigan Department of Health and Human Services Staff present and participating remotely:

Tulika Bhattacharya
Marcus Connolly
Beth Nagel
Brenda Rogers

II. Declaration of Conflicts of Interests

None.

III. Review of Agenda

Motion by Dr. Trivax, seconded by Dr. Alaswad to accept the agenda as presented. Motion carried.

IV. Review of Draft Minutes – November 22, 2020

Motion by Mr. Sheiko, seconded by Dr. Ali to accept the minutes as presented. Motion carried.

V. Charges 4 and 5:
Charge 4 - Review if diagnostic cardiac catheterization services should be allowed to be performed in ambulatory surgical centers (ASCs)
Charge 5 - Determine if elective PCI procedures should be allowed to be performed in ASCs

Chairperson Madder and Dr. Qureshi provided an overview of the new Section X.(1), (2), and (3). (Attachment A)

Discussion followed.

Motion by Mr. Sheiko, seconded by Dr. Felten to adopt 250 PCI sessions as the primary operator at an attending level, and change "or" to "and" in the title of the section.

Discussion followed on the motion.

Roll call vote:

Wunderly – no response
Trivax – yes
Timmis – no response

Saltiel – yes
Saab – yes
Qureshi – yes
Porter – yes
Koneru – yes
Hart – no
Fernandez – no
Felten – yes
Daher – yes
Alaswad – yes
Ali – yes
Sheiko – yes
Madder – yes

Motion carried.

Discussion continued.

The subcommittee will continue work on these subsections by clarifying if these requirements are applicable to an FSOF or ASC as well as clarifying that this does not cover primary PCI.

Dr. Trivax provided an overview of the new Section X.(4) and (5).

Discussion followed.

Motion by Dr. Madder, seconded by Mr. Sheiko to adopt the requirements of subsections (4) and (5) as presented.

Discussion followed on the motion.

Roll call vote:

Wunderly – no response
Trivax – yes
Timmis – no response
Saltiel – yes
Saab – yes
Qureshi – yes
Porter – yes
Koneru – yes
Hart – yes
Fernandez – yes
Felten – yes
Daher – yes
Alaswad – no response

Ali - yes
Sheiko – yes
Madder – yes

Motion carried.

Dr. Daher provided an overview of the new Section X.(7) – (10).

Discussion followed.

The subcommittee will do further work on subsection (10) regarding the registry.

Motion by Dr. Saltiel, seconded by Dr. Madder to adopt subsections (7) – (10) which includes deleting "hospital" in subsection (10).

Discussion followed on the motion.

Roll call vote:

Wunderly – yes
Trivax – yes
Timmis – no response
Saltiel – yes
Saab – yes
Qureshi – yes
Porter – yes
Koneru – yes
Hart – yes
Fernandez – yes
Felten – yes
Daher – yes
Alaswad – no response
Ali – yes
Sheiko – yes
Madder – yes

Motion carried.

Chairperson Madder provided an overview of the new Section X.(11) and (12).

Discussion followed.

Motion by Dr. Daher, seconded by Dr. Trivax to adopt subsections (11) and (12) with a change to 300 procedure equivalents for diagnostic cardiac catheterizations in (12)(a).

Discussion followed on the motion.

Roll call vote:

Wunderly – no response
Trivax – yes
Timmis – yes
Saltiel – no
Saab – yes
Qureshi – no
Porter – no response
Koneru – yes
Hart – no
Fernandez – no
Felten – no
Daher – yes
Alaswad – no response
Ali – no response
Sheiko – yes
Madder – yes

Motion failed.

VI. Charge 7:
Review if pacemakers and implantable cardioverter defibrillator (ICD) implants should be allowed to be performed in ASCs

Chairperson Madder provided the subcommittee update.

VII. Next Steps

Updates from subcommittees.

VIII. Future Meeting Dates

January 14, 2021 & February 18, 2021

IX. Public Comment

1. Brett Jackson, Economic Alliance for Michigan (EAM)
2. Susan Heck, Corazon
3. Paul Singh, MD

X. Adjournment

Motion by Dr. Saltiel, seconded by Dr. Timmis to adjourn the meeting at 9:49 a.m. Motion carried.

ORIGINAL

Section 4. Requirements to initiate primary or elective PCI Services without on-site OHS services

Sec. 4. An applicant hospital proposing to initiate primary or elective PCI services without on-site OHS services shall demonstrate the following:

(1) The applicant hospital operates an adult diagnostic cardiac catheterization service that has performed a minimum of 500 procedure equivalents that includes 400 procedure equivalents in the category of cardiac catheterization procedures during the most recent 12 months preceding the date the application was submitted to the Department.

(2) The applicant hospital has at least two interventional cardiologists to perform the PCI procedures and each cardiologist has performed at least 50 PCI sessions annually as the primary operator during the most recent 24-month period preceding the date the application was submitted to the Department.

(3) The nursing and technical catheterization laboratory staff: are experienced in handling acutely ill patients and comfortable with interventional equipment; have acquired experience in dedicated interventional laboratories at an OHS hospital; and participate in an un-interrupted 24-hour, 365-day call schedule. Competency shall be documented annually.

Section X. Requirements to initiate ~~primary~~ diagnostic cardiac catheterization or elective PCI Services ~~without on-site OHS services~~ at an FSOF

Sec. X. An applicant ~~hospital~~ proposing to initiate ~~primary~~ diagnostic cardiac catheterization or elective PCI services ~~without on-site OHS services~~ at an FSOF shall demonstrate the following:

~~(1) The applicant hospital operates an adult diagnostic cardiac catheterization service that has performed a minimum of 500 procedure equivalents that includes 400 procedure equivalents in the category of cardiac catheterization procedures during the most recent 12 months preceding the date the application was submitted to the Department~~.

(2) The applicant ~~hospital~~ has identified at least ~~two~~ one interventional cardiologist~~s~~ to perform the diagnostic and PCI procedures and ~~each~~ the cardiologist has performed at least 50 PCI sessions annually as the primary operator during the most recent 24-month period preceding the date the application was submitted to the Department. The interventional cardiologist must have completed an interventional cardiology fellowship training program, be board certified in interventional cardiology, have performed a total of at least 100 PCI sessions as the primary operator, and have a minimum of 2 years experience at an attending level.

(3) The applicant has identified nursing and technical catheterization laboratory staff that are experienced in handling acutely ill patients and comfortable with interventional equipment~~;~~ and have acquired experience in dedicated interventional laboratories at an OHS hospital~~; and participate in an un-interrupted 24-hour, 365-day call schedule~~. Competency shall be documented annually.

ORIGINAL

Section 4. Requirements to initiate primary or elective PCI Services without on-site OHS services (continued)

(4) The laboratory or laboratories are equipped with optimal imaging systems, resuscitative equipment, and intra-aortic balloon pump (IABP) support, and stocked with a broad array of interventional equipment.

(5) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management. Competency shall be documented annually.

(4) The laboratory or laboratories ~~are~~ will be equipped with optimal imaging systems, resuscitative equipment, and intra-aortic balloon pump (IABP) support, and stocked with a broad array of interventional equipment. The laboratories will be equipped with systems for assessing hemodynamic significance of coronary lesions (i.e. FFR, iFR, or other) and intracoronary imaging technology (i.e. IVUS or OCT) for ensuring PCI optimization.

(5) The applicant has identified cardiac care unit nurses who are adept in hemodynamic monitoring and IABP management. Competency shall be documented annually.

ORIGINAL

Section 4. Requirements to initiate primary or elective PCI Services without on-site OHS services (continued)

(6) A written agreement with an OHS hospital that includes all of the following:

(a) Involvement in credentialing criteria and recommendations for physicians approved to perform PCI procedures.

(b) Provision for ongoing cross-training for professional and technical staff involved in the provision of PCI to ensure familiarity with interventional equipment. Competency shall be documented annually.

(c) Provision for ongoing cross training for emergency department, catheterization laboratory, and critical care unit staff to ensure experience in handling the high acuity status of PCI patient candidates. Competency shall be documented annually.

(d) Regularly held joint cardiology/cardiac surgery conferences to include review of all PCI cases.

(e) Development and ongoing review of patient selection criteria for PCI patients and implementation of those criteria.

(f) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for prompt care.

(g) Written protocols, signed by the applicant hospital and the OHS hospital, for the immediate transfer within 60 minutes travel time from the cardiac catheterization laboratory to evaluation on site in the OHS hospital, of patients requiring surgical evaluation and/or intervention 365 days a year. If the applicant hospital meets the requirements of subsection (13)(c), then the OHS hospital can be more than 60 minutes travel time from the proposed site. The protocols shall be reviewed and tested on a quarterly basis.

(h) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for the provision of interventional procedures.

(6) A written agreement with an OHS hospital that includes all of the following:

(a) Involvement in credentialing criteria and recommendations for physicians approved to perform PCI procedures.

(b) Provision for ongoing cross-training for professional and technical staff involved in the provision of PCI to ensure familiarity with interventional equipment. Competency shall be documented annually.

~~(c) Provision for ongoing cross training for emergency department, catheterization laboratory, and critical care unit staff to ensure experience in handling the high acuity status of PCI patient candidates. Competency shall be documented annually.~~

(d) Regularly held joint cardiology~~/cardiac surgery~~ catheterization laboratory conferences to include review of ~~all~~ PCI cases.

(e) Development and ongoing review of patient selection criteria for PCI patients and implementation of those criteria.

(f) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for prompt care.

(g) Written protocols, signed by the applicant ~~hospital~~ and the OHS hospital, for the immediate transfer within 60 minutes travel time from the cardiac catheterization laboratory to evaluation on site in the OHS hospital, of patients requiring surgical evaluation and/or intervention 365 days a year. ~~If the applicant hospital meets the requirements of subsection (13)(c), then the OHS hospital can be more than 60 minutes travel time from the proposed site.~~ The protocols shall be reviewed and tested on a quarterly basis.

(h) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for the provision of interventional procedures.

ORIGINAL

Section 4. Requirements to initiate primary or elective PCI Services without on-site OHS services (continued)

(7) A written protocol must be established and maintained for case selection for the performance of PCI.

(8) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid transfer from the emergency department to the cardiac catheterization laboratory must be developed and maintained so that door-to-balloon targets are met.

(9) At least two physicians credentialed to perform PCI must commit to functioning as a coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate with administrative and clinical staff in establishing and implementing protocols, call schedules, and quality assurance procedures pertaining to PCI designed to meet the requirements for this certification and in keeping with the current guidelines for the provision of PCI without on-site OHS services promulgated by the American College of Cardiology and American Heart Association.

(10) The applicant hospital shall participate in a data registry administered by the Department or its designee as a means to measure quality and risk adjusted outcomes within PCI services without on-site OHS services, and the applicant hospital shall identify a physician point of contact for the data registry.

(7) A written protocol must be established and maintained for case selection for the performance of PCI consistent with ~~. Applicants are encouraged to use~~ the case selection criteria documented in the SCAI Position Statement on the Performance of Percutaneous Coronary Intervention in Ambulatory Surgical Centers (Box et al. Catheter Cardiovasc Interv. 2020;1-9)

(8) ~~A system to ensure prompt and efficient identification of potential primary PCI patients and rapid transfer from the emergency department to the cardiac catheterization laboratory must be developed and maintained so that door-to-balloon targets are met.~~

(9) ~~At least two physicians credentialed to perform PCI must commit to functioning as a coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate with administrative and clinical staff in establishing and implementing protocols, call schedules, and quality assurance procedures pertaining to PCI designed to meet the requirements for this certification and in keeping with the current guidelines for the provision of PCI without on-site OHS services promulgated by the American College of Cardiology and American Heart Association.~~

(10) The applicant hospital shall participate in a data registry administered by the Department or its designee as a means to measure quality and risk adjusted outcomes within PCI services without on-site OHS services, and the applicant hospital shall identify a physician point of contact for the data registry.

ORIGINAL

Section 4. Requirements to initiate primary or elective PCI Services without on-site OHS services (continued)

(11) Cath lab facility requirements and collaborative cardiologists-heart surgeon relationship requirements shall conform to all SCAI/ACC Guidelines for PCI Services Without On-Site OHS including the SCAI/ACC/AHA Expert Consensus Document. The applicant hospital shall be liable for the cost of demonstrating compliance with these criteria in their application.

(12) The applicant hospital shall project the following based on data from the most recent 12-month period preceding the date the application was submitted to the Department, as applicable. (a) If the applicant hospital is applying for a primary PCI service without open heart surgery, the applicant hospital shall project a minimum of 36 primary PCI procedures per year. (b) If the applicant hospital is applying for an elective PCI service without on-site OHS, the applicant hospital shall project a minimum of 200 PCI procedures per year.

(11) Cath lab facility requirements ~~and collaborative cardiologists-heart surgeon relationship requirements~~ shall conform to the ~~all SCAI/ACC Guidelines for PCI Services Without On-Site OHS including~~ the SCAI~~/ACC/AHA Expert Consensus Document~~ Position Statement on the Performance of Percutaneous Coronary Intervention in Ambulatory Surgical Centers (Box et al. Catheter Cardiovasc Interv. 2020;1-9). The applicant ~~hospital~~ shall be liable for the cost of demonstrating compliance with ~~these criteria~~ the principles documented in this position statement in their application.

(12) The applicant ~~hospital~~ shall project the following based on data from the most recent 12-month period preceding the date the application was submitted to the Department, as applicable.

~~(a) If the applicant hospital is applying for a primary PCI service without open heart surgery, the applicant hospital shall project a minimum of 36 primary PCI procedures per year.~~ If the applicant is applying for diagnostic cardiac catheterization service, the applicant shall project a minimum of 600 procedure equivalents per year in the category of adult diagnostic cardiac catheterizations.

(b) If the applicant ~~hospital~~ is applying for an elective PCI service ~~without on-site OHS~~, the applicant ~~hospital~~ shall project a minimum of 200 PCI procedures per year.

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Section 4. Requirements to initiate primary or elective PCI Services without on-site OHS services (continued)

(13) If the applicant hospital is applying for an elective PCI service without on-site OHS, the applicant hospital also shall demonstrate the following: (a) The applicant hospital operated a primary PCI service for at least one year prior to the date of application. (b) The applicant hospital submitted data to a data registry administered by the Department or its designee and been found to have acceptable performance as compared to the registry benchmarks for the most recent 12 months prior to the date of application. (c) If the applicant hospital was not approved as a primary PCI service prior to September 14, 2015, then, in addition, the applicant hospital shall demonstrate that there is no PCI or OHS service within 60 radius miles or 60 minutes travel time from the proposed site.

(14) If the applicant hospital is currently providing OHS services and therapeutic cardiac catheterization services and is proposing to discontinue OHS services and therapeutic cardiac catheterization services, then the applicant hospital shall apply to initiate primary or elective PCI services without on-site OHS using this section. The applicant hospital shall demonstrate all of the requirements in this section except for subsection (13) and is subject to all requirements in Section 10.

(13) ~~If the applicant hospital is applying for an elective PCI service without on-site OHS, the applicant hospital also shall demonstrate the following:~~

~~(a) The applicant hospital operated a primary PCI service for at least one year prior to the date of application.~~

~~(b) The applicant hospital submitted data to a data registry administered by the Department or its designee and been found to have acceptable performance as compared to the registry benchmarks for the most recent 12 months prior to the date of application.~~

~~(c) If the applicant hospital was not approved as a primary PCI service prior to September 14, 2015, then, in addition, the applicant hospital shall demonstrate that there is no PCI or OHS service within 60 radius miles or 60 minutes travel time from the proposed site.~~

(14) ~~If the applicant hospital is currently providing OHS services and therapeutic cardiac catheterization services and is proposing to discontinue OHS services and therapeutic cardiac catheterization services, then the applicant hospital shall apply to initiate primary or elective PCI services without on-site OHS using this section. The applicant hospital shall demonstrate all of the requirements in this section except for subsection (13) and is subject to all requirements in Section 10.~~

Section 12. Documentation of projections

Add new (1)…Note this language was adapted from the CON Review Standards for CT Scanner Services.

(1) An applicant shall demonstrate that the projected number of procedure equivalents to be performed at the proposed site are based on historical volumes from the most recent 12-month period verifiable by the Department immediately preceding the date of the application from an existing cardiac catheterization service that is in compliance with the volume requirements applicable to that service, and will continue to be in compliance with the volume requirements applicable to that service subsequent to the initiation of the proposed cardiac catheterization service. Only excess procedure equivalents equal to or greater than what is being committed pursuant to this subsection may be used to document projections under this section. In demonstrating compliance with this subsection, an applicant shall provide each of the following:

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Section 12. Documentation of projections

(3) An applicant hospital proposing to initiate an elective PCI service without on-site OHS services shall demonstrate and certify that the hospital shall treat 200 or more patients with PCI annually using data during the most recent 12-month period preceding the date the application was submitted to the Department as follows:
(a) All primary PCIs performed at the applicant hospital.
(b) All inpatients transferred from the applicant hospital to another hospital for PCI.
(c) 90% of patients who received diagnostic cardiac catheterizations at the applicant hospital and received an elective PCI at another hospital within 30 days of the diagnostic catheterization (based on physician commitments).
(d) 50% of the elective PCI procedures performed by the committing physician at another hospital within 120 radius miles or 120 minutes travel time from the applicant hospital for patients who did not receive diagnostic cardiac catheterization at the applicant hospital (based on physician commitments).
(e) An applicant hospital with current OHS services and therapeutic cardiac catheterization services that is proposing to discontinue OHS services and therapeutic cardiac catheterization services and is applying to initiate primary or elective PCI services without on-site OHS services may count all primary and elective PCI at the applicant hospital within the most recent 12-month period preceding the date the application was submitted to the Department.

Section 12. Documentation of projections continued

(3) An applicant ~~hospital~~ proposing to initiate an elective PCI service ~~without on-site OHS services~~ shall demonstrate and certify that the ~~hospital~~ proposed service shall treat ~~200~~ 400 or more patients with PCI annually using data from ~~during~~ the most recent 12-month period preceding the date the application was submitted to the Department as follows and applicable:

(a) All primary PCIs performed at the applicant hospital.

(b) All inpatients transferred from the applicant hospital to another hospital for PCI.

(c) 90% of patients who received diagnostic cardiac catheterizations at the applicant ~~hospital~~ facility and received an elective PCI at another ~~hospital~~ cardiac catheterization service within 30 days of the diagnostic catheterization (based on physician commitments).

(d) ~~50%~~ 100% of the elective PCI procedures performed by the committing physician at another ~~hospital~~ cardiac catheterization service within ~~120 radius~~ 20 miles if proposed service is located in a metropolitan county, or 75 miles if located in a rural or micropolitan county ~~or 120 minutes travel time~~ from the ~~applicant hospital~~ proposed service for patients who did not receive diagnostic cardiac catheterization at the applicant ~~hospital~~ facility (based on physician commitments).

(e) An applicant hospital with current OHS services and therapeutic cardiac catheterization services that is proposing to discontinue OHS services and therapeutic cardiac catheterization services and is applying to initiate primary or elective PCI services without on-site OHS services may count all primary and elective PCI at the applicant hospital within the most recent 12-month period preceding the date the application was submitted to the Department.

Section 12. Documentation of projections continued

Add new (4)…Note this language was adapted from the CON Review Standards for CT Scanner Services.

(4) An applicant required to project procedure equivalents shall utilize data verifiable by the Department from the most recent 12-month period preceding the date the application was submitted to the Department as follows and applicable:

(a) All excess diagnostic cardiac and peripheral catheterizations performed at the applicant facility.

(b) All procedures performed by the committing physician at another cardiac catheterization service within 20 miles if proposed service is located in a metropolitan county, or 75 miles if located in a rural or micropolitan county from the proposed service and not performed at the applicant facility (based on physician commitments).

Section 2. Definitions

(1) For purposes of these standards:

Add new (r)…Note adapted from the CON Review Standards for CT Scanner Services.

(r) “Excess procedure equivalents” means the number of procedure equivalents performed by an existing cardiac catheterization service in excess of 1200 per cardiac catheterization laboratory, 400 procedure equivalents in the category of adult diagnostic catheterization, and 300 PCIs. The number of cardiac catheterization laboratories used to compute excess procedure equivalents shall include both existing and approved but not yet operational cardiac catheterization laboratories. In the case of a cardiac catheterization service that operates or has a valid CON to operate more than one laboratory at the same site, the term means number of procedure equivalents in excess of 1200 multiplied by the number of cardiac catheterization laboratories at the same site. For example, if a cardiac catheterization service operates, or has a valid CON to operate, 2 cardiac catheterization laboratories at the same site, the excess procedure equivalents is the number that is in excess of 2400 procedure equivalents, of which at least 400 are in the category of adult diagnostic cardiac catheterization, and in excess of 300 PCIs.

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Section 10. Project delivery requirements and terms of approval for all applicants

Sec. 10. An applicant hospital shall agree that, if approved, the cardiac catheterization service and all existing and approved laboratories shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory located within a hospital, and have within, or immediately available to the room, dedicated emergency equipment to manage cardiovascular emergencies.

(b) The service shall be staffed with sufficient medical, nursing, technical and other personnel to permit regular scheduled hours of operation and continuous 24-hour on-call availability. (c) The medical staff and governing body shall receive and review at least annual reports describing the activities of the cardiac catheterization service including complication rates, morbidity and mortality, success rates and the number of procedures performed.

Section 10. Project delivery requirements and terms of approval for all applicants

Sec. 10. An applicant ~~hospital~~ shall agree that, if approved, the cardiac catheterization service and all existing and approved laboratories shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory ~~located within a hospital, and have~~ that has within, or immediately available to the room, dedicated emergency equipment to manage cardiovascular emergencies.

(b) The service shall be staffed with sufficient medical, nursing, technical and other personnel to permit regular scheduled hours of operation and continuous 24-hour on-call availability.

(c) The medical staff and governing body shall receive and review at least annual reports describing the activities of the cardiac catheterization service including complication rates, morbidity and mortality, success rates and the number of procedures performed.

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Section 10. Project delivery requirements and terms of approval for all applicants continued

(d) Each physician credentialed by a hospital to perform diagnostic left-heart catheterization and/or coronary angiography must perform, as the primary operator, an average of at least 50 diagnostic cardiac catheterization sessions involving a left-heart catheterization or coronary angiography per year averaged over the most recent 2 years starting in the second 12 months after being credentialed. This two year average will be evaluated on a rolling basis annually thereafter. The annual case load for a physician means a cardiac catheterization session in which that physician performed, as the primary operator, at least one left-heart catheterization or coronary angiography, in any combination of hospitals. Physicians falling below this volume requirement must be placed on a focused professional practice evaluation (FPPE) plan, which must include an independent review of all diagnostic cardiac catheterization sessions by an appropriate designee, to ensure quality outcomes are maintained. In the event a physician does not perform cardiac catheterization procedures on a temporary or permanent basis for a period of 3 months or more, the physician diagnostic procedure volume will be annualized on the 24-month period preceding the absence. When a diagnostic cardiac catheterization session and ad hoc therapeutic cardiac catheterization session are performed together, diagnostic and therapeutic sessions are counted separately for the purposes of this subsection. If a physician is doing right heart only procedures, then they are not required to meet this volume requirement. Physicians who are credentialed by a hospital to perform adult therapeutic cardiac catheterization procedures are not required to meet the volume requirement for diagnostic cardiac catheterization sessions.

Section 10. Project delivery requirements and terms of approval for all applicants continued

(d) Each physician credentialed by a ~~hospital~~ facility to perform diagnostic left-heart catheterization and/or coronary angiography must perform, as the primary operator, an average of at least 50 diagnostic cardiac catheterization sessions involving a left-heart catheterization or coronary angiography per year averaged over the most recent 2 years starting in the second 12 months after being credentialed. This two year average will be evaluated on a rolling basis annually thereafter. The annual case load for a physician means a cardiac catheterization session in which that physician performed, as the primary operator, at least one left-heart catheterization or coronary angiography, in any combination of ~~hospitals~~ facilities. Physicians falling below this volume requirement must be placed on a focused professional practice evaluation (FPPE) plan, which must include an independent review of all diagnostic cardiac catheterization sessions by an appropriate designee, to ensure quality outcomes are maintained. In the event a physician does not perform cardiac catheterization procedures on a temporary or permanent basis for a period of 3 months or more, the physician diagnostic procedure volume will be annualized on the 24-month period preceding the absence. When a diagnostic cardiac catheterization session and ad hoc therapeutic cardiac catheterization session are performed together, diagnostic and therapeutic sessions are counted separately for the purposes of this subsection. If a physician is doing right heart only procedures, then they are not required to meet this volume requirement. Physicians who are credentialed by a hospital to perform adult therapeutic cardiac catheterization procedures are not required to meet the volume requirement for diagnostic cardiac catheterization sessions.

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Section 10. Project delivery requirements and terms of approval for all applicants continued

(e) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization procedures shall perform, as the primary operator, an average of at least 50 adult therapeutic cardiac catheterization sessions per year averaged over the most recent two years starting in the second 12 months after being credentialed. This two-year average will be evaluated on a rolling basis annually thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization sessions performed by that physician in any combination of hospitals. Physicians falling below this volume requirement must be placed on a focused professional practice evaluation (FPPE) plan, which must include an independent review of all therapeutic cardiac catheterization sessions by an appropriate designee, to ensure quality outcomes are maintained. In the event a physician does not perform cardiac catheterization procedures on a temporary or permanent basis for a period of 3 months or more, the physician therapeutic procedure volume will be annualized on the 24-month period preceding the absence. When a diagnostic cardiac catheterization session and ad hoc therapeutic cardiac catheterization session are performed together, diagnostic and therapeutic sessions are counted separately for the purposes of this subsection (this includes interventional cardiologists and electrophysiologists). For interventional cardiologists, the therapeutic session volume excludes pacemaker and ICD implantation. For electrophysiologists, pacemaker and ICD implants performed in an operating room may also be counted toward the physician therapeutic volume

Section 10. Project delivery requirements and terms of approval for all applicants continued

(e) Each physician credentialed by a ~~hospital~~ facility to perform adult therapeutic cardiac catheterization procedures shall perform, as the primary operator, an average of at least 50 adult therapeutic cardiac catheterization sessions per year averaged over the most recent two years starting in the second 12 months after being credentialed. This two-year average will be evaluated on a rolling basis annually thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization sessions performed by that physician in any combination of ~~hospitals~~ facilities. Physicians falling below this volume requirement must be placed on a focused professional practice evaluation (FPPE) plan, which must include an independent review of all therapeutic cardiac catheterization sessions by an appropriate designee, to ensure quality outcomes are maintained. In the event a physician does not perform cardiac catheterization procedures on a temporary or permanent basis for a period of 3 months or more, the physician therapeutic procedure volume will be annualized on the 24-month period preceding the absence. When a diagnostic cardiac catheterization session and ad hoc therapeutic cardiac catheterization session are performed together, diagnostic and therapeutic sessions are counted separately for the purposes of this subsection (this includes interventional cardiologists and electrophysiologists). For interventional cardiologists, the therapeutic session volume excludes pacemaker and ICD implantation. For electrophysiologists, pacemaker and ICD implants performed in an operating room may also be counted toward the physician therapeutic volume

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Section 10. Project delivery requirements and terms of approval for all applicants continued

(f) Each physician credentialed by a hospital to perform pediatric/congenital cardiac catheterizations shall perform, as the primary operator, an average of at least 50 pediatric/congenital cardiac catheterization sessions per year averaged over the most recent 2 years starting in the second 12 months after being credentialed. This two-year average will be evaluated on a rolling basis annually thereafter. The annual case load for a physician means pediatric/congenital cardiac catheterization sessions performed by that physician in any combination of hospitals. Physicians falling below this volume requirement must be placed on a focused professional practice evaluation (FPPE) plan, which must include an independent review of all cardiac catheterization sessions by an appropriate designee, to ensure quality outcomes are maintained. In the event a physician does not perform cardiac catheterization procedures on a temporary or permanent basis for a period of 3 months or more, the physician therapeutic procedure volume will be annualized on the 24-month period preceding the absence.

(g) An adult diagnostic cardiac catheterization service shall have a minimum of two physicians on its active hospital staff meeting the following criteria:
(i) are trained consistent with the recommendations of the American College of Cardiology;
(ii) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and
(iii) have performed a minimum of 100 adult diagnostic cardiac catheterization sessions in the preceding 12 months. The annual case load for a physician means a cardiac catheterization session in which that physician performed, as the primary operator, at least one diagnostic cardiac catheterization, in any combination of hospitals.

Section 10. Project delivery requirements and terms of approval for all applicants continued

(f) Each physician credentialed by a hospital to perform pediatric/congenital cardiac catheterizations shall perform, as the primary operator, an average of at least 50 pediatric/congenital cardiac catheterization sessions per year averaged over the most recent 2 years starting in the second 12 months after being credentialed. This two-year average will be evaluated on a rolling basis annually thereafter. The annual case load for a physician means pediatric/congenital cardiac catheterization sessions performed by that physician in any combination of hospitals. Physicians falling below this volume requirement must be placed on a focused professional practice evaluation (FPPE) plan, which must include an independent review of all cardiac catheterization sessions by an appropriate designee, to ensure quality outcomes are maintained. In the event a physician does not perform cardiac catheterization procedures on a temporary or permanent basis for a period of 3 months or more, the physician therapeutic procedure volume will be annualized on the 24-month period preceding the absence.

(g) An adult diagnostic cardiac catheterization service shall have a minimum of two physicians on its active ~~hospital~~ staff meeting the following criteria:
(i) are trained consistent with the recommendations of the American College of Cardiology;
(ii) are credentialed by the ~~hospital~~ facility to perform adult diagnostic cardiac catheterizations; and
(iii) have performed a minimum of 100 adult diagnostic cardiac catheterization sessions in the preceding 12 months. The annual case load for a physician means a cardiac catheterization session in which that physician performed, as the primary operator, at least one diagnostic cardiac catheterization, in any combination of ~~hospitals~~ facilities.

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Section 10. Project delivery requirements and terms of approval for all applicants continued

(h) An adult therapeutic cardiac catheterization service shall have a minimum of two physicians on its active hospital staff meeting the following criteria:
(i) are trained consistent with the recommendations of the American College of Cardiology;
(ii) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and
(iii) have performed a minimum of 50 adult therapeutic cardiac catheterization sessions in the preceding 12 months. The annual case load for a physician means a cardiac catheterization session in which that physician performed, as the primary operator, at least one therapeutic cardiac catheterization, in any combination of hospitals.

(i) A pediatric/congenital cardiac catheterization service shall have at least one physician on its active hospital staff meeting the following criteria:
(i) is board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;
(ii) is credentialed by the hospital to perform pediatric/congenital cardiac catheterizations; and
(iii) has trained consistently with the recommendations of the American College of Cardiology.

Section 10. Project delivery requirements and terms of approval for all applicants continued

(h) An adult therapeutic cardiac catheterization service shall have a minimum of two physicians on its active hospital staff meeting the following criteria:
(i) are trained consistent with the recommendations of the American College of Cardiology;
(ii) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and
(iii) have performed a minimum of 50 adult therapeutic cardiac catheterization sessions in the preceding 12 months. The annual case load for a physician means a cardiac catheterization session in which that physician performed, as the primary operator, at least one therapeutic cardiac catheterization, in any combination of hospitals.

(i) A pediatric/congenital cardiac catheterization service shall have at least one physician on its active hospital staff meeting the following criteria:
(i) is board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;
(ii) is credentialed by the hospital to perform pediatric/congenital cardiac catheterizations; and
(iii) has trained consistently with the recommendations of the American College of Cardiology.

Section 10. Project delivery requirements and terms of approval for all applicants continued

(j) A pediatric/congenital cardiac catheterization service shall maintain a quality assurance plan as outlined in the most current ACCF/SCAI Guidelines.

(k) A cardiac catheterization service shall be directed by an appropriately trained physician. The Department shall consider appropriate training of the director if the physician is board certified in cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The director of an adult cardiac catheterization service shall have performed at least 100 catheterizations per year during each of the five preceding years. The Department may accept other evidence that the director is appropriately trained.

(l) A cardiac catheterization service shall be operated consistently with the recommendations of the American College of Cardiology.

(m) The applicant hospital providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service shall participate with a data registry administered by the Department or its designee that monitors quality and risk adjusted outcomes.

Section 10. Project delivery requirements and terms of approval for all applicants continued

(j) A pediatric/congenital cardiac catheterization service shall maintain a quality assurance plan as outlined in the most current ACCF/SCAI Guidelines.

(k) A cardiac catheterization service shall be directed by an appropriately trained physician. The Department shall consider appropriate training of the director if the physician is board certified in cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The director of an adult cardiac catheterization service shall have performed at least 100 catheterizations per year during each of the five preceding years. The Department may accept other evidence that the director is appropriately trained.

(l) A cardiac catheterization service shall be operated consistently with the recommendations of the American College of Cardiology.

(m) The applicant ~~hospital~~ facility providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service shall participate with a data registry administered by the Department or its designee that monitors quality and risk adjusted outcomes.

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Section 10. Project delivery requirements and terms of approval for all applicants continued

(3) Compliance with the following access to care requirements:

(a) The service shall accept referrals for cardiac catheterization from all appropriately licensed practitioners.

(b) The service shall participate in Medicaid at least 12 consecutive months within the first two years of operation and annually thereafter.

(c) The service shall not deny cardiac catheterization services to any individual based on ability to pay or source of payment.

(d) The operation of and referral of patients to the cardiac catheterization service shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.1621; MSA 14.15 (16221).

Section 10. Project delivery requirements and terms of approval for all applicants continued

(3) Compliance with the following access to care requirements:

(a) The service shall accept referrals for cardiac catheterization from all appropriately licensed practitioners.

(b) The service shall participate in Medicaid at least 12 consecutive months within the first two years of operation and annually thereafter.

(c) The service shall not deny cardiac catheterization services to any individual based on ability to pay or source of payment.

(d) The operation of and referral of patients to the cardiac catheterization service shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.1621; MSA 14.15 (16221).

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Section 10. Project delivery requirements and terms of approval for all applicants continued

(4) Compliance with the following monitoring and reporting requirements:

(a) The service shall be operating at or above the applicable volumes in the second 12 months of operation of the service, or an additional laboratory, and annually thereafter:
(i) 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.
(ii) 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.
(iii) 600 procedure equivalents in the category of pediatric/congenital cardiac catheterization procedures.
(iv) 500 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.
(v) 750 procedure equivalents for a hospital in a metropolitan county with one laboratory.
(vi) 1,000 procedure equivalents per cardiac catheterization laboratory for two or more laboratories.
(vii) 36 adult primary PCI cases for a primary PCI service without on-site OHS service.
(viii) 200 adult PCI procedures for an elective PCI service without on-site OHS service.

(b) The applicant hospital shall participate in a data collection network established and administered by the Department or its designee. Data may include, but is not limited to, annual budget and cost information, operating schedules, patient demographics, morbidity and mortality information, and payor. The Department may verify the data through on-site review of appropriate records.

Section 10. Project delivery requirements and terms of approval for all applicants continued

(4) Compliance with the following monitoring and reporting requirements:

(a) The service shall be operating at or above the applicable volumes in the second 12 months of operation of the service, or an additional laboratory, and annually thereafter:
(i) 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.
(ii) 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.
(iii) 600 procedure equivalents in the category of pediatric/congenital cardiac catheterization procedures.
(iv) 500 procedure equivalents for a ~~hospital~~ facility in a rural or micropolitan county with one laboratory.
(v) 750 procedure equivalents for a ~~hospital~~ facility in a metropolitan county with one laboratory.
(vi) 1,000 procedure equivalents per cardiac catheterization laboratory for two or more laboratories.
(vii) 36 adult primary PCI cases for a primary PCI service without on-site OHS service.
(viii) 200 adult PCI procedures for an elective PCI service without on-site OHS service.

(b) The applicant ~~hospital~~ facility shall participate in a data collection network established and administered by the Department or its designee. Data may include, but is not limited to, annual budget and cost information, operating schedules, patient demographics, morbidity and mortality information, and payor. The Department may verify the data through on-site review of appropriate records.

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Section 10. Project delivery requirements and terms of approval for all applicants continued

(c) The applicant hospital providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service shall participate in a data registry administered by the Department or its designee as a means to measure quality and risk adjusted outcomes within cardiac catheterization services. The Department or its designee shall require that the applicant hospital submit summary reports as specified by the Department. The applicant hospital shall provide the required data in a format established by the Department or its designee. The applicant hospital shall be liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The applicant hospital shall become a member of the data registry specified by the Department upon initiation of the service and continue to participate annually thereafter for the life of that service.

(d) the applicant hospital shall provide the department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.

Section 10. Project delivery requirements and terms of approval for all applicants continued

(c) The applicant ~~hospital~~ facility providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service shall participate in a data registry administered by the Department or its designee as a means to measure quality and risk adjusted outcomes within cardiac catheterization services. The Department or its designee shall require that the applicant hospital submit summary reports as specified by the Department. The applicant hospital shall provide the required data in a format established by the Department or its designee. The applicant hospital shall be liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The applicant ~~hospital~~ facility shall become a member of the data registry specified by the Department upon initiation of the service and continue to participate annually thereafter for the life of that service.

(d) the applicant ~~hospital~~ facility shall provide the department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.

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Section 10. Project delivery requirements and terms of approval for all applicants continued

(5) Compliance with the following primary and elective PCI requirements for hospitals providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service, if applicable:

(a) The requirements set forth in Section 4.

(b) The hospital shall immediately report to the Department any changes in the interventional cardiologists who perform the primary PCI procedures.

(c) The hospital shall maintain a 90-minute door-to-balloon time or less in at least 75% of the primary PCI sessions (excluding patients with cardiogenic shock).

Section 10. Project delivery requirements and terms of approval for all applicants continued

(5) Compliance with the following primary and elective PCI requirements for ~~hospitals~~ facilities providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service, if applicable:

(a) The requirements set forth in Section 4.

(b) The hospital shall immediately report to the Department any changes in the interventional cardiologists who perform the primary PCI procedures.

(c) The hospital shall maintain a 90-minute door-to-balloon time or less in at least 75% of the primary PCI sessions (excluding patients with cardiogenic shock).

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Section 10. Project delivery requirements and terms of approval for all applicants continued

(d) The applicant hospital shall participate in a data registry administered by the Department or its designee as a means to measure quality and risk adjusted outcomes within PCI services by service level. The Department or its designee shall require that the applicant hospital submit all consecutive PCI cases performed within the hospital and meet data submission timeliness requirements and threshold requirements for PCI data submission, accuracy and completeness established by a data registry administered by the Department or its designee. The applicant hospital shall provide the required data in a format established by the Department or its designee. The applicant hospital shall be liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The applicant hospital shall become a member of the data registry specified by the Department upon initiation of the service and continue to participate annually thereafter for the life of that service. At a minimum, the applicant hospital shall report the following:

(i) the number of patients treated with and without STEMI,
(ii) the proportion of PCI patients with emergency CABG or required emergent transfer,
(iii) risk and reliability adjusted patient mortality for all PCI patients and a subset of patients with STEMI,
(iv) PCI appropriate use in elective non-acute MI cases, and
(v) rates of ad-hoc multi-vessel PCI procedures in the same session.

Section 10. Project delivery requirements and terms of approval for all applicants continued

(d) The applicant ~~hospital~~ facility shall participate in a data registry administered by the Department or its designee as a means to measure quality and risk adjusted outcomes within PCI services by service level. The Department or its designee shall require that the applicant hospital submit all consecutive PCI cases performed within the ~~hospital~~ facility and meet data submission timeliness requirements and threshold requirements for PCI data submission, accuracy and completeness established by a data registry administered by the Department or its designee. The applicant ~~hospital~~ facility shall provide the required data in a format established by the Department or its designee. The applicant ~~hospital~~ facility shall be liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The applicant ~~hospital~~ facility shall become a member of the data registry specified by the Department upon initiation of the service and continue to participate annually thereafter for the life of that service. At a minimum, the applicant ~~hospital~~ facility shall report the following:

(i) the number of patients treated with and without STEMI,
(ii) the proportion of PCI patients with emergency CABG or required emergent transfer,
(iii) risk and reliability adjusted patient mortality for all PCI patients and a subset of patients with STEMI,
(iv) PCI appropriate use in elective non-acute MI cases, and
(v) rates of ad-hoc multi-vessel PCI procedures in the same session.

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Section 10. Project delivery requirements and terms of approval for all applicants continued

(e) The applicant hospital shall maintain a physician point of contact for the data registry.

(f) For primary PCI services without on-site OHS service and elective PCI services without on-site OHS service, catheterization lab facility requirements and collaborative cardiologists-heart surgeon relationship requirements shall conform to all SCAI/ACC Guidelines for PCI including the SCAI/ACC/AHA Expert Consensus Document. The applicant hospital shall be liable for the cost of demonstrating compliance with these criteria.

(g) The Department shall use these thresholds and metrics in evaluating compliance: performance at a level above the 50th percentile of the statewide performance on each metric listed under subsection (d)(ii) – (v) or another level provided by the data registry designee and accepted by the Department.

Section 10. Project delivery requirements and terms of approval for all applicants continued

(e) The applicant ~~hospital~~ facility shall maintain a physician point of contact for the data registry.

(f) For primary PCI services without on-site OHS service and elective PCI services without on-site OHS service, catheterization lab facility requirements and collaborative cardiologists-heart surgeon relationship requirements shall conform to all SCAI/ACC Guidelines for PCI including the SCAI/ACC/AHA Expert Consensus Document. The applicant ~~hospital~~ facility shall be liable for the cost of demonstrating compliance with these criteria.

(g) The Department shall use these thresholds and metrics in evaluating compliance: performance at a level above the 50th percentile of the statewide performance on each metric listed under subsection (d)(ii) – (v) or another level provided by the data registry designee and accepted by the Department.

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Section 10. Project delivery requirements and terms of approval for all applicants continued

(h) The Department shall notify those hospitals who fail to meet any of the minimally acceptable objective quality metric thresholds including those under subsection (d)(ii) – (v). The Department shall require these hospitals to:
(i) submit a corrective action plan within one month of notification and
(ii) demonstrate that performance has improved to meet or exceed all applicable objective quality metric thresholds, including those under subsection (d)(ii) – (v), within 12 months of notification.

(i) The applicant hospital initiating elective PCI without on-site OHS services shall have Accreditation for Cardiovascular Excellence (ACE) accreditation or an equivalent body perform an on-site review within 3, 6, and 12 months after implementation. The applicant hospital shall submit the summary reports of the on-site review to the Department and maintain on-going accreditation.

Section 10. Project delivery requirements and terms of approval for all applicants continued

(h) The Department shall notify those ~~hospitals~~ facilities who fail to meet any of the minimally acceptable objective quality metric thresholds including those under subsection (d)(ii) – (v). The Department shall require these ~~hospitals~~ facilities to:

(i) submit a corrective action plan within one month of notification and

(ii) demonstrate that performance has improved to meet or exceed all applicable objective quality metric thresholds, including those under subsection (d)(ii) – (v), within 12 months of notification.

(i) The applicant ~~hospital~~ facility initiating elective PCI without on-site OHS services shall have Accreditation for Cardiovascular Excellence (ACE) accreditation or an equivalent body perform an on-site review within 3, 6, and 12 months after implementation. The applicant ~~hospital~~ facility shall submit the summary reports of the on-site review to the Department and maintain on-going accreditation.

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Section 10. Project delivery requirements and terms of approval for all applicants continued

(6) Nothing in this section prohibits the Department from taking compliance action under MCL 333.22247.

(7) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant hospital or its authorized agent.

Section 10. Project delivery requirements and terms of approval for all applicants continued

(6) Nothing in this section prohibits the Department from taking compliance action under MCL 333.22247.

(7) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant hospital or its authorized agent.